

ISO 9000:2000 — THE NEW INTERNATIONAL STANDARD FOR QUALITY

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SINCE ITS ORIGINAL CONCEPTION IN 1987, SOME 250,000 ORGANIZATIONS AROUND THE WORLD HAVE REGISTERED

for ISO 9000, a series of international standards that establishes Quality Management System (QMS) requirements. While ISO 9000 received minor revisions in 1994, radical revisions have been made in the year 2000, creating a revised standard now called ISO 9000:2000.

The revised standard will require the organizations that have previously been certified to update their current quality systems.

It will also change the ground rules for the tens and even hundreds of thousands of organizations that are seeking, or will seek, registration in the future. National standards bodies, registrars and consultants will now have to contend with a whole new set of challenges and opportunities.

Like its predecessor, ISO 9000:2000 is a series of interrelated documents (three in ISO 9000:2000), each with a different function: ISO 9000 deals with fundamentals and vocabulary; ISO 9001, which is the heart of the new revision, states the requirements for the new system; and ISO 9004 provides guidance for its implementation.

In view of the impact of this revision and the costs it will entail, organizations understandably have many questions and concerns: Do we have to register to the new standard? Will our current certification need to be changed? Why the change? What is the difference between the old ISO and the new ISO? How will it change the way we run our business? Who will benefit from the new standard? Who will be hurt? Will it be more difficult to implement the new ISO than the old ISO?

COMPARING ISOs

The two standards offer a different model for quality. ISO 9000:1994 defines quality around 20 key elements a company uses to effectively and consistently produce the products and services it provides customers. Originally, the standard was designed for manufacturing companies, although it can, and has been,

adapted to apply to processing companies and service organizations. The primary purpose was to assure customers that the certified company produces products at a consistent level of quality.

ISO 9000:2000 is quite different from the original standard. The new standard is based on a process model that any enterprise can use, whether they are a manufacturer, a

chemical processor or a service provider. Instead of 20 elements as in the old standard, the process model of the new standard has four major sections (Sections 0 through 4 provide background and logistical information):

- *Section 5: Management responsibility.*
- *Section 6: Resource management.*
- *Section 7: Product realization.*
- *Section 8: Measurement, analysis and improvement.*

Sections 5 through 8 contain all the requirements for the new ISO standard. Using more generic, and less prescriptive terms, than ISO 9000:1994, ISO 9000:2000 makes it easier for all types

THE NEW STANDARD REQUIRES ORGANIZATIONS TO UPDATE THEIR OLD ISO 9000 PROGRAMS.

of enterprises to adapt their operations to the new ISO standard.

The requirements are a quantum leap forward and in line with progressive thinking in the quality field. The model's four major sections function similarly to the Plan-Do-Check-Act (PDCA) improvement process popularized by W. Edwards Deming. This is much more rigorous than the 1994 ISO's watchwords: "Do what you document, document what you do, and prove it."

QUANTUM LEAPS

The quantum leaps featured in ISO 9000:2000 focus on customer input, continual improvement, resource management and management responsibility.

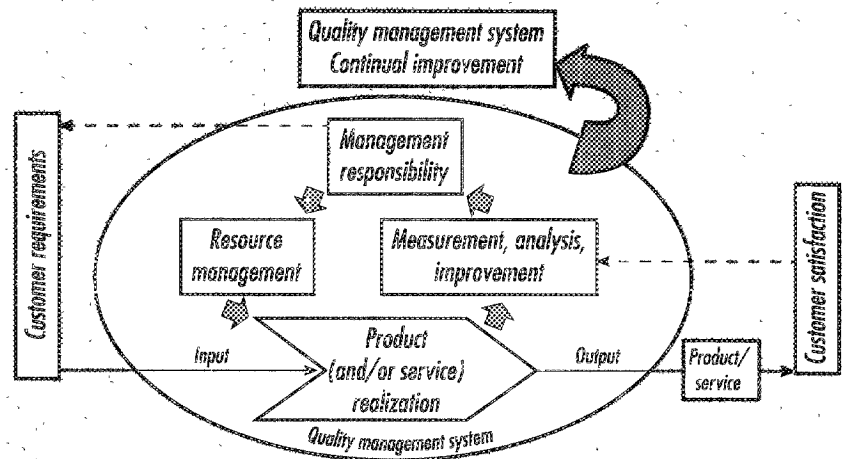
Figure 1 is a graphic depiction of the process model, showing the power of the customer under the new standard. Customer requirements drive the input, while customer satisfaction drives the output. Organizations will need procedures in place to describe and monitor the needs and desires of each customer's order and for measuring and analyzing customer satisfaction.

In regard to continual improvements, it will not be enough for an organization to measure customer satisfaction. It will be necessary to improve the level of satisfaction, which requires a way to measure and improve internal processes. Continuous improvement is a core theme in ISO 9000:2000, and is inherent in the model's structure.

Continually improving defect rates, with consequent increased customer satisfaction, is a core value of Deming and total quality management (TQM). Although many, including the authors of this article, believe that continual improvement was always implied in ISO 9000, continual improvement is now a clearly defined requirement.

In regards to resource management, the 1994 standard contained a paragraph that required management to provide all necessary resources. These provisions are expanded in the 2000 revision. The resource management section of the new standard spells out a wide range of resources that should be utilized. These include human resources, the availability of adequate numbers of competent people, training necessary to assure competence, infrastructure, work environment, safety, ergonomics, hygiene, suppliers, partners and financial resources.

PROCESS MODEL FOR ISO 9000:2000



Management's role in the previous ISO 9000 required it to establish quality policy, commit adequate resources, conduct a management review and appoint a management representative to supervise the QMS. However, for the most part, under ISO 9000:1994, the quality management system was largely the responsibility of quality professionals, not upper management.

Executive management plays a far more central role with the new standard. In ISO 9000:2000, management responsibility is expanded so that management presides over a multi-step version of the process:

- *Devising policies.*
- *Establishing objectives and procedures for reviewing quality.*
- *Developing a plan to identify the resources necessary to meet established objectives.*
- *Organizing and establishing a quality management system (QMS).*
- *Establishing a management review program.*

Management review requirements have been expanded in the new standard. Management must specifically check the policies and objectives of the QMS to find ways where improvements can be made.

OLD TO NEW

Every element of its predecessor can be mapped onto the new ISO 9001. Moreover, since the new version requires written procedures, the familiar four-tier pyramid structure for documentation need not change, although it can be simplified under the new standard. Thus, an organi-

zation's current ISO system can be the foundation for its successor.

On the other hand, much of the existing documentation may need to be remapped and expanded to meet the requirements of ISO 9000:2000. In many cases, these revisions are substantial. As an indication of the degree of change, 12 of the elements in ISO 9000:1994 have been reduced to sub-clauses in its successor.

In addition, some new procedures must be created to accommodate new requirements and subject matter. However, much of what is new in ISO will not be new to many well-run companies. Virtually every business enterprise, or entrepreneur, understands that to be successful, an organization must:

- *Have an effective strategic business planning process in place*
- *Carefully monitor the needs and requirements of its customers*
- *Satisfy its customers*
- *Have a full array of metrics to measure the performance of its internal processes and its success at satisfying its customers*
- *Continually seek to improve its operations, products and services.*

Most well-managed organizations will already have business processes in place to reach at least some of these objectives of the new ISO 9000:2000 standard.

ADVANTAGES AND DISADVANTAGES

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TOTAL QUALITY MANAGEMENT

Customers will also benefit. Consequently, ISO 9001:2000 will have far more weight with customers than did its predecessor. If an enterprise enjoyed a marketing advantage because it was registered to the 1994 ISO, the new ISO should give it an even greater edge.

Many companies have a QMS and a business management system. However, ISO 9000:2000 encourages enterprises to combine the two systems. In the past, the vast majority of certifications were in manufacturing. By contrast, the new version is purposely more generic so that it can be applied more universally. The new standard is as applicable to a medical facility or a school as it is to a manufacturing facility. With a broader appeal, there is no reason why the number of certifications under the 2000 revision should not double.

The downside of the new standard is that it requires currently certified organizations to invest additional time and resources in order to meet the new standard's requirements. However, some organizations will find this less of a challenge than others will. Companies that have achieved ISO 9000 as a means of improving their business processes will have an edge.

Companies that have made only a minimal commitment to ISO 9000, who embraced it as a way to gain a marketing advantage or meet the demands of customers, may feel the new ISO 9000 hurts them. Nevertheless, ISO 9000:2000 offers considerable advantages for them and their customers.

TRANSITION

The transition is essentially the same whether a company was registered ISO 9001, 9002 or 9003. ISO 9001:2000 contains a clause ("1.2 Permissible Exclusions") for excluding or modifying requirements so that companies registered under the old ISO 9002 and ISO 9003 can adapt their quality management systems to ISO 9001:2000. ISO 9002 and 9003 thus become obsolete.

With publication of the new standard, an organization has a maximum of three years to adopt the standard. In those three years, quality management systems conforming to the 1994 or 2000 standard will be acceptable. To meet the deadline, it is expected that organizations will start adopting the new requirements during their surveillance audits. Thus, if all goes according to plan, the

conversion process should be complete by the beginning of 2004.

As a rule of thumb, organizations that are in the process of registering to ISO 9000 or who want or need to get registered by the end of 2000, can register to the current 1994 version. Still, they should begin modeling their system

around ISO 9000:2000 in anticipation of the conversion that follows.

In general, the implementation process should not be significantly different for the 2000 revision than it was for the previous version. Under ISO 9001:2000, businesses will no longer have the option of excluding activities they actually perform. Under the new regime, if you do it, you must include it as part of your ISO 9001 system.

By incorporating such factors as customer satisfaction and continual improvement, ISO 9000:2000 moves closer to the principles of TQM than its predecessor. At the same time, it retains the discipline of third party assessment, registration and surveillance that has made ISO 9000 so successful. It is an inevitable evolution, which offers substantial benefits to organizations, their customers, and their suppliers. ■

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